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Approved By:

Emily Scott, Agricultural Attaché

Prepared By:

Jana Mikulasova, Agricultural Specialist

Report Highlights:

Since acreage devoted to genetically engineered (GE) crop production peaked in 2008, Slovak farmers and politicians have gradually turns their backs on agricultural biotechnology. In 2017 (and 2018) Slovak farmers ceased planting Bt corn altogether, as demand for GE products has dwindled under the influence of anti-biotech non-governmental organizations (NGOs), retailers, and neighboring countries (Austria, Hungary, and Germany). The Slovak government has altered its position, from accepting GE technology to setting the goal of making Slovakia a "GMO-free" zone. There is currently proposed legislation, which would allow limiting or banning cultivation on national level.

Executive Summary:

Slovak farmers began planting genetically engineered (GE) crops in 2006 with production peaking in 2008. Since 2010, however, acreage devoted to Bt corn production has dramatically decreased until 2017 (and 2018) when farmers halted plantings altogether. Demand for GE products, specifically including meat and dairy produced from animals fed GE-feed, has dwindled under the influence of antibiotech non-governmental organizations (NGOs), retailers, and neighboring countries (Austria, Hungary, and Germany). Where the Slovak government was previously supportive of biotechnology, they have since changed their stance, again likely in response to local messages originating from antibiotech NGOs and activist groups. Specifically in 2016, one local, anti-GE group organized a petition, "For Healthy Foodstuffs and Slovakia Without Genetically Modified Organisms," which garnered over 18,300 signatures. The Petition was presented to the Minister of Agriculture who responded favorably to the group and their Petition, noting that her ambition is to make Slovakia a, "GMO free zone." However, the proposed legislative amendment, which would allow Slovakia to introduce national bans on GE-products is still underway and has yet to be finalized. Slovakia has no stated opinion on New Breeding Technologies and awaits the European Court of Justice's decision. There are no genome edited animals and/or clones under development or in commercial production in Slovakia.

General Information:

TABLE OF CONTENTS

Report Highlights
Executive Summary

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: Production and Trade

PART B: Policy
PART C: Marketing

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: Production and Trade

PART E: Policy
PART F: Marketing

CHAPTER1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a. Product development:

There are currently no GE crops under development in Slovakia.

b. Commercial production:

Slovakia was previously one of a few EU member states with a science-based approach to biotechnology. Slovak farmers grew Bt corn MON 810 since 2006 until 2016, using it mainly for biogas production and for on-farm cattle feed. However, the growing influence of neighboring countries' anti-GE positions and the difficulties in marketing and exporting GE-products halted Slovak GE production. Specifically, major retail buyers (German and Austrian owned retail chains) have increasingly demanded "GMO-free" products including products from animals that were never fed any GE feed, which resulted in zero Bt corn planting in 2017.

| Area (HA) of GE Crops in Slovakia | | | | | | | | | | | | | |
|-----------------------------------|----------|----------|----------|----------|-----------|----------|-----|----------|----------|----------|----------|----------|----------|
| | 200 6 | 200 7 | 200 8 | 200 9 | 201 0 | 201 1 | 201 | 201 3 | 201 4 | 201 5 | 201 6 | 201 7 | 201 8 |
| Bt corn MO N 810 | 30 | 930 | 1,93 | 875 | 1,24 9 | 761 | 189 | 100 | 411 | 104 | 122 | 0 | 0 |

Source: Ministry of Agriculture

c. Exports:

Slovakia does not export GE products. When Slovak farmers grew MON 810, they preferred to use the corn product on the farm as animal feed or as a feedstock for biogas production. This allowed farmers to avoid navigating the complicated and limiting demands of importing countries, such as Germany or Austria.

d. Imports:

Slovakia has no bans on importing of GE crops and imports bioengineered soybean meal, a main protein source for feed mixes.

In 2017, Slovak soybean meal imports totaled 90,093 metric tons (MT). Major suppliers are the neighboring European states. Soybean imports are trans-shipped to Slovakia through the main European ports in the Netherlands and Germany. As a result, the exact origin of soy shipments from the United States or any exporting country is difficult to quantify.

| Slovakia Import Statistics | | | | | | | | | | |
|---------------------------------|------|----------|--------|--------|--------|-------------|--------|-----------|--|--|
| Commodity: Soybean meal, (2017) | | | | | | | | | | |
| Calendar Year: 2015 - 2017 | | | | | | | | | | |
| Partner | Unit | Quantity | | | | % Change | | | | |
| Country | | 2015 | 2016 | 2017 | 2015 | 2016 | 2017 | 2017/2016 | | |
| World Total | MT | 108,571 | 80,658 | 90,093 | 100.00 | 100.00 | 100.00 | 11.70 | | |
| Hungary | MT | 29,731 | 11,249 | 19,404 | 27.38 | 13.95 | 21.54 | 72.49 | | |
| Germany | MT | 24,115 | 17,561 | 15,330 | 22.21 | 21.77 | 17.02 | - 12.70 | | |
| Netherlands | MT | 21,308 | 12,514 | 11,306 | 19.63 | 15.51 | 12.55 | - 9.65 | | |
| Slovenia | MT | 1,851 | 10,440 | 10,211 | 1.71 | 12.94 | 11.33 | - 2.20 | | |
| Czech Republic | MT | 11,000 | 7,742 | 9,690 | 10.13 | 9.60 | 10.76 | 25.17 | | |
| Poland | MT | 8,882 | 9,213 | 9,044 | 8.18 | 11.42 | 10.04 | - 1.83 | | |
| Austria | MT | 8,382 | 8,448 | 8,704 | 7.72 | 10.47 | 9.66 | 3.03 | | |
| Italy | MT | 1,826 | 2,188 | 3,497 | 1.68 | 2.71 | 3.88 | 59.87 | | |

Source: Global Trade Atlas

e. Food aid:

Slovakia is not a food aid recipient and consequently faces no issues related to biotechnology that would impede the importation of food aid donations. Food aid to other countries is typically done through large international organizations by financial contribution. When a food product is donated directly, there are no issues related to biotechnology, as the majority of food production in Slovakia is conventional.

f. Trade barriers:

There are no trade barriers stemming from the current legislation. However, the Slovak Minister of Agriculture and Rural Development, Gabriela Matecna, has publically expressed her aim to make Slovakia a "GMO-free" zone. The Slovak Ministries of Agriculture and Environment are planning to update related Slovak legislation in order to achieve that goal.

PART B: POLICY

a. Regulatory framework:

Slovakia follows the EU legislation and the harmonized national legislation. The main legislative act is Act No. 151/2002 Coll. on the Use of Genetic Technologies and Genetically Modified Organisms (i.e. The GMO Act) that came into force April 1, 2002. The Act was amended by the Acts No. 587/2004 Coll., No. 77/2005 Coll., No. 100/2008 Coll., Act no. 117/2010 Coll, and 448/2012 Coll. The executing legislation for the GMO Act is Decree 399/2005, as amended by Decree no. 312/2008 and Decree no. 86/2013.

Currently, a legislative update is being developed to implement the EU Directive 2015/412 that gives the Member States the ability to restrict or prohibit the cultivation of "GMOs" in their territory. Slovakia neighbors, including Austria and Hungary, have both taken advantage of this Directive.

The Ministry of Environment of the Slovak Republic (MoE) is the national competent authority for the implementation of The GMO Act. The MoE issues permits for contained use of GE-products, and permits for their release into the environment for trial purposes. The MoE receives applications for placing on the market, which are then reviewed and approved or rejected in collaboration with other EU member states and institutions of the European Union. MoE established the *Biosafety Committee and its Panel of Experts* on the basis of the Act No.151/2002 Coll., art. 27. The Committee is formed by eleven permanent members and fifteen experts. Administration of the Committee is under the MoE's Department of Biosafety. The Committee provides recommendations upon MoE request. The recommendations are prepared based on its members' specific areas of expertise. The relevant documents and results of the Committee activities are published on the MoE website.

The Ministry of Agriculture (MoA) is the competent authority for food and feed made from GE products and for cultivation of GE agricultural plants on the EU market.

The MOA and the MoE both provide scientific advice in the decision-making process regarding adoption and cultivation of GE products. The MoA, through its Department for Food Safety and Nutrition (DFSN), established the *National Advisory Experts Group in the field of GMOs and New Foodstuffs*. The group is composed of approximately 40 experts from a wide range of disciplines relevant to the field of GE food safety and cooperates internationally.

Ministry of Health (MoH) is the competent authority for medicines produced from GE products and for using GE products in area of public feeding. The MoH has representation in MoE's Biosafety committee and is an official partner to DG SANCO (Directorate General for Health and Consumer Affairs) of European Commission. It is the competent authority to the Biological and Toxin Weapons Convention (BTWC, 1972).

The Slovak positions for negotiations on approvals of GE products in the EU are prepared by MoE in collaboration with the MoA.

Consolidated text of the Slovak biotech-related legislation in English is available here: http://www.gmo.sk/en/?page=144.

b. Approvals:

Because GE approvals are made on the EU level, information regarding bioengineered crops approved for cultivation, and food or feed use can be found in the EU-28 Agricultural Biotechnology Annual Report available at: http://gain.fas.usda.gov/Lists/Advanced%20Search/AllItems.aspx.

c. Stacked or pyramided event approvals:

Slovakia implements EU legislation, for more information please see the EU-28 Agricultural Biotechnology Annual Report.

d. Field testing:

The last time Slovakia conducted field trials with GE crops was in 2013. A strong influence of the neighboring anti-GMO countries and policy shifts resulted in abandoning field testing. From the regulatory point of view, however, it is still possible to conduct field trials in Slovakia. In the past researchers tested several events of corn with various modifications including pest and herbicide resistance and changed nutritional characteristics (increased content of mannose), and sugar beet tolerant to herbicide products containing glyphosate.

e. Innovative biotechnologies:

Slovakia does not have any stated position on New Breeding Techniques. Slovak authorities are awaiting the European Court of Justice (ECJ) decision.

f. Coexistence:

The rules for coexistence in Slovakia are laid down in the Act no. 184/2006 Coll. (updated by Act no. 78/2008) that sets the obligation to the farmers to announce to other farmers within the radius of minimal isolation distance of intent to cultivate genetically modified plants. This Decree No. 69/2007 sets the minimum isolation distances as follows:

| Crop / Distance in meters | Corn | Rapeseed | Sugar Beets | Potatoes |
|---------------------------|------|----------|-------------|----------|
| Conventional Agriculture | 200 | 400 | 50 | 20 |
| Organic Agriculture | 300 | 600 | 50 | 20 |

A two meters isolation distance can be replaced by a buffer zone consisting of one row of conventional corn (for corn) or by one meter of conventional sugar beets (for sugar beets).

g. Labeling:

Labeling is enforced by local authorities and follows EU labeling standards. Packaged foods and feeds derived and/or containing biotechnology enhanced ingredients must be labeled. "Contains GMOs" is a typical example of a product label statement found on the market. For more information on EU biotechnology labeling requirements see the EU-28 Biotechnology Annual Report.

The Association of Feed Producers, Warehouse-keepers and Trade Companies of Slovakia developed a voluntary GMO fee certification scheme. The scheme allows growers, feed producers, traders, and animal producers and processors to label their product GMO free.

Another option for voluntary GMO free labeling in Slovakia is the German standard VLOG (Verband Lebensmittel ohne Gentechnik) offered by the Association of the Agricultural Entrepreneurs of Slovakia.





h. Monitoring and testing:

The Slovak Environment Inspection (SEI), Department of Biosafety is the inspection body that controls compliance with the Act and Decree on the use of genetic techniques and genetically modified organisms, laid down in legal regulations and duties resulting from the decisions issued by the Ministry of Environment. For analytical services, SEI collaborates with the Institute of Molecular Biology SAS, which serves as a reference laboratory for MoE and SEI.

The State Veterinary and Food Administration executes the control of import, production, manipulation, handling, and marketing of genetically modified food and feed. The Central Control and Testing Institute of Agriculture is responsible, among other things, for the control of manipulation with the genetically modified seeds and their planting. The last two mentioned authorities have DNA laboratories serving as reference laboratories for MoA.

i. Low level presence (LLP) policy:

Slovakia follows the "technical solution" guidance of an allowance of 0.1 percent outlined in EU

Regulation 619/2011. This regulation lays down the methods of sampling and analysis of official control of feed regarding the presence of genetically modified organisms for which an authorization procedure is pending or the authorization of which has expired. The Institution responsible for control and testing of feed imports is the Central Control and Testing Institute in Agriculture (<u>UKSUP</u>).

j. Additional regulatory requirements:

N/A

k. Intellectual property rights (IPR):

Slovakia adheres to EU legislation for IPR. The national regulation pertaining to protection of new plant varieties is Act no. 202/2009, which incorporates the principles of the International Union for the Protection of new Varieties of Plants (<u>UPOV</u>) system. The Central Control and Testing Institute in Agriculture (<u>UKSUP</u>) is the responsible body for this area.

1. Cartagena protocol ratification:

Slovakia ratified the Cartagena Protocol on February 22, 2004. All regulations of the Cartagena Protocol on Biosafety are in place. The MoE is the Competent Authority relating to the Cartagena Protocol on Biosafety. More details can be found at the Biosafety Clearing House, Slovak Republic website: http://bch.gmo.sk.

Slovakia ratified the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress (for damage resulting from transboundary movements of living modified organisms) to the Cartagena Protocol on Biosafety on April 29, 2015 and accessed the Nagoya Protocol on Access and Benefitsharing on March 28, 2016.

m. International treaties/forums:

Slovakia is a member of the Plant Protection Convention, the Codex Alimentarius Commission (CAC), Organization for Economic Co-operation and Development (OECD), UN Food and Agriculture Organization (FAO), and World Trade Organization (WTO). The country has not been taking any significantly noteworthy positions within international forums.

n. Related issues:

Slovakia joined the <u>Danube Soya</u> initiative when Slovak State Secretary, Magdalena Lacko-Bartosova, signed the *Danube Soya Declaration* on January 17, 2015. On July 18, 2017, Slovakia signed the *European Soya Declaration*.

Those initiatives support further development of markets for sustainably cultivated non-GE soybeans and soybean products as well as the establishment of transparent product labeling systems based on certified production standards. The European Soya Declaration signatories also support the development of partnerships, including between EU and non-EU countries such as Ukraine, Moldova, Serbia, and Bosnia-Herzegovina, so that more sustainable, certified soybeans are cultivated, processed, and traded in Europe.

PART C: MARKETING

a. Public/private opinions:

Several NGOs and activists groups opposed to agricultural biotechnologies and GE production are active in Slovakia. Their websites and blogs frequently contain negative and factually inaccurate information on "GMOs," genetically engineered crops, and related issues. One such group, "Slovakia Without GMOs" (their website is translated to "*Everything about GMO*," www.vsetkoogmo.sk) organized a petition, "For Healthy Foodstuffs and Slovakia Without Genetically Modified Organisms." They collected 18,300 signatures from Slovak citizens and delivered the petition to the Slovak Government in November, 2016.

The petition has seven points or "asks," as follows:

- 1. Banning cultivation of genetically engineered crops and sales of genetically engineered seeds in Slovakia
- 2. Mandatory labeling of products containing genetically engineered ingredients throughout the whole production cycle, including animal products from animals that were fed genetically engineered events
- 3. Transparency of all discussions and voting of those responsible for approvals of genetically engineered organisms and their introduction into the environment in Slovakia. Allowing general public and consumer representatives being part of the *Biosafety Committee and its Panel of Experts*
- 4. Intensive support of research and development aimed at breeding of new resistant breeds and hybrids and renewal of old traditional breeds of crops suitable for Slovak conditions as well as for addressing the climate change
- 5. Intensive support of a development of independent consultants in agriculture that will be focused on sustainable chemicals-free and organic production of healthy foodstuffs with regards to environmental protection, biodiversity and climate change adaptation
- 6. Intensive support of organic agriculture and family farms by minimum of 15 percent of the agrarian sector budget. Doubling the 2012 organic area and production by 2020. Organic products to all schools
- 7. Enforcing, on a European and international level, independent assessment of GMOs on human health and eco-systems

The Minister of Agriculture, Gabriela Matecna, met with the petition committee representatives on December 9, 2016, and Minister Matcena responded to the petition in writing on December 20, 2016. The official written response to the petition, from the Minister was very accepting in tone, stating that, "on the side of the Ag Ministry, a zero tolerance for GM crops is in place," and continues, "The Ministry has been working on a system, which will guarantee that the final products for consumers will be GMO free. Likewise, the Ministry has ambitions to make Slovakia a GMO free zone."

The letter further acknowledges that the MoA understands the negative stance from the general public towards cultivation of genetically engineered crops. It mentions that the MoE informally promised to the MoA to start with the legislative process of implementing the EU Directive (EU) 2015/412 into national legislation at the beginning of 2017. This would allow limiting or banning cultivation of genetically engineered crops in Slovakia. Until now – mid 2018 – the legislative process, however, is unfinished and the amendment of the pertinent Slovak legislation is still in the form of a draft.

Since Slovakia did not opt out of this legislation during the "transition period" ending October 3, 2015, which allowed opting out for non-scientific reasons, using "substantial grounds", for example specific environmental or agricultural issues, they will now have to opt out under new measures. Those must be in conformity with Union law, reasoned, proportional and non-discriminatory and, in addition, based on compelling grounds such as those related to: (a) environmental policy objectives; (b) town and country planning; (c) land use; (d) socioeconomic impacts; (e) avoidance of GMO presence in other products without prejudice to Article 26a; (f) agricultural policy objectives; (g) public policy. According to the EU Directive 2015/412, a Member State may adopt those measures and restrict or prohibit the cultivation in all or part of its territory of a GMO, or of a group of GMOs defined by crop or trait, once authorized in accordance with Part C of this Directive or with Regulation (EC) No 1829/2003. Providing such reasoning might require additional resources Slovakia might not currently have in place.

The MoE was forwarded the points three and seven of the petition. The MoE official responded on December 19, 2016 and included information on where decisions are published online, how the general public can comment on applications for approvals of genetically engineered events, and the role of the *Biosafety Committee and its Panel of Experts*. Further, they explain labeling requirements as laid out in national and EU legislation. The MoE has since allowed representatives from NGOs to become the members of the Biosafety Committee.

b. Market acceptance/studies:

Farmers face difficulties in marketing Bt corn both domestically and in export markets. Major retail buyers of meat and milk and dairy products push for GE-free production and require farmers to guarantee that their livestock were not fed with bioengineered events. As a reaction to this requirement, the area of Bt corn planted has decreased in the last few years resulting in zero hectares of Bt corn planting in 2017 and 2018.

Also, Slovakia's major export markets for agrarian products are neighboring EU countries, such as Hungary, Austria and Germany, where use/import of GE products is even more limited with even stronger consumer sentiments against these GE products. FAS Prague is not aware of any recent market studies.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

Cloning is an animal biotechnology that developers frequently utilize in conjunction with other animal biotechnologies such as genetic engineering and are therefore included in this report.

PART D: PRODUCTION AND TRADE

a. Product development:

In Slovakia there are no genetically engineered animals or cloning under commercial development. Cloned or GE animals used for research purposes, which are notified and authorized for contained use, are primarily rodents.

b. Commercial production:

In Slovakia there are no commercial applications approved for GE animals for food or feed use, and no notification of the use of GE animals for food use or other agricultural use has been filed with the EU. Likewise, there are no commercial applications of animal cloning.

c. Exports:

N/A

d. Imports:

Slovakia imports genetics from other countries and some of them originate from clones.

e. Trade barriers:

The main trade barriers are stemming from the general EU policies and public opposition, as described in the EU-28 Agricultural Biotechnology Annual Report available at: http://gain.fas.usda.gov/Lists/Advanced%20Search/AllItems.aspx.

PART E: POLICY

a. Regulatory framework:

Genetically engineered animals are regulated in the same way as any other genetically engineered organisms in Slovakia. The main legislative act for that area is the Act No. 151/2002 Coll. on the Use of Genetic Technologies and Genetically Modified Organisms that came into force from April 1, 2002, as amended. The use of genetically engineered animals in food and feed is regulated by different legislative acts – for food it is a part of the Food Codex dedicated to novel foods, the feed area falls under responsibilities of the MoA.

The projects using GE animals that have been authorized in Slovakia so far fall under the scope of contained use. The authorized GE animals are classified as risk category 1 or 2 (minimal risk). Authorization process is following: The entity that intends to use GE animals notifies the MoE. The notification must include a risk assessment, a description of proposed containment measures, and a description of proposed handling of the GE products, which must include the transport, storage, and disposal of waste.

b. Innovative biotechnologies:

Slovakia does not have any stated position on New Breeding Techniques. Slovak authorities are awaiting the ECJ decision.

c. Labeling and traceability:

Slovakia follows the EU regulations for labeling and traceability. Recently, retail chains have required a certification that milk and meat they buy from their suppliers come from animals not fed GE feed. They are requiring this in order to label the product as "GMO-free." Therefore Slovakia, as well as other EU states developed a voluntary certification scheme.

d. Intellectual property rights (IPR):

Slovakia adheres to EU IPR legislation. In Slovakia there is no specific legislation addressing intellectual property rights for animal biotechnologies on a national level.

e. International treaties/forums:

Slovakia is a member of the World Organization for Animal Health (OIE), CAC, OECD, FAO, and WTO. The country has not been taking any significantly noteworthy positions within international forums.

f. Related issues:

N/A

PART F: MARKETING

a. Public/private opinions:

So far there have not been significant discussions on the topic of animal biotech or cloning that would divide the general public into distinctive opinion groups.

b. Market acceptance/studies:

FAS Prague is not aware of any market studies related to animal biotechnology and genetically engineered animals.